

200.1079CON7

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Serial No.: 10/057,632  
Applicant: Ronald M. Burch, et al.  
Filed: January 25, 2002  
Art Unit: 1639  
Examiner: Bennett M. Celsa  
For: **Analgesic Combination of Oxycodone and N-[3-(formylamino)  
4-oxo-6-phenoxy-4h-1-benzopyran-7yl] methanesulfonamide**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

November 4, 2004

**INFORMATION DISCLOSURE STATEMENT**

Sir:

In accordance with Applicant's duty of disclosure under 37 C.F.R. §1.56 and the provisions of 37 C.F.R. §§ 1.97 and 1.98, Applicants hereby make of record the single document listed on the accompanying Form PTO-1449 for consideration by the Examiner in connection with the examination of the above-identified patent application.

The document reports the assessment of the effects of combined administration of oxycodone with either of celecoxib, etodolac or rofecoxib, as performed by Purdue Pharma L.P., which is associated with the assignee of the present invention.

This Information Disclosure Statement is being filed after a First Office Action but before a Final Office Action or Notice of Allowance. Pursuant to 37 C.F.R. § 1.98(c), a check for \$180.00 is enclosed to cover the required fee. However, if it is determined that any fee is due, the Examiner is authorized to charge said fee to Attorney Deposit Account No. 50-0552.

It is respectfully requested that the reference cited on the accompanying Form PTO-1449 be considered and made of record.

Respectfully submitted,

DAVIDSON, DAVIDSON & KAPPEL, LLC

By: 

Robert J. Paradiso  
Reg. No. 41,240

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New York, New York 10018  
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FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE  <b>LIST OF PRIOR ART CITED BY APPLICANT</b>  (Use several sheets if necessary)			ATTY. DOCKET NO.: 200.1079CON7		SERIAL NO.: 10/057,632	
					APPLICANT(S): Ronald BURCH et al.			
					FILING DATE: January 25, 2002		GROUP: 1639	

U.S. PATENT DOCUMENTS									
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE		
	AA								
	AB								
	AC								

FOREIGN PATENT DOCUMENTS									
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION		
							Yes	No	
	AD								

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)		
	AE	Purdue Discovery Research, Department of Neuropharmacology Study Report "Assessment of the Effects of Combined Administration of Oxycodone and Cox II inhibitors, Celecoxib, Etodolac and Rofecoxib, in the Rat FCA Model of Inflammatory Pain"; July 28, 2003
	AF	
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EXAMINER		DATE CONSIDERED
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Sir:

In accordance with Applicant's duty of disclosure under 37 C.F.R. §1.56 and the provisions of 37 C.F.R. §§ 1.97 and 1.98, Applicants hereby make of record the references listed on the accompanying Form PTO-1449 (1 page) for consideration by the Examiner in connection with the examination of the above-identified patent application. In accordance with 37 C.F.R. § 1.98 (a), copies of the listed references are enclosed.

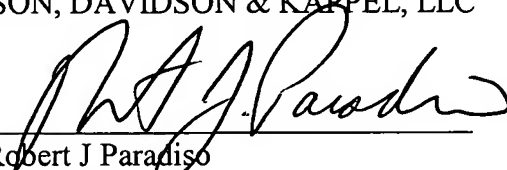
The present Information Disclosure Statement is filed under 37 C.F.R. §1.97(b), after the mailing of a first Office Action on the merits. Accordingly, a fee of \$ 180.00 is enclosed. However, if it is determined that there is a deficiency or an overpayment, the Examiner is authorized to charge said deficiency or credit said overpayment to Attorney Deposit Account No. 50-0552.

It is respectfully requested that the reference cited on the accompanying Form PTO-1449 be considered and made of record.

Respectfully submitted,

DAVIDSON, DAVIDSON & KAPPEL, LLC

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<b>FOREIGN PATENT DOCUMENTS</b>							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
							Yes      No
	AF						
<b>OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>							
	AG	Friedel et al., "Nabumetone- A Reappraisal of its Pharmacology and Therapeutics Use in Rheumatic Diseases," Drugs Vol. 45 (1): pp. 131-156 (1993)					
	AH	Eversmeyer et al., "Safety Experience With Nabumetone Versus Diclofenac, Naproxen, Ibuprofen, and Piroxicam in Osteoarthritis and Rheumatoid Arthritis, The American Journal of Medicine, Vol. 95 (Suppl. 2A) pp. 10S-18S					
	AI	Engelhardt et al., "Anti-inflammatory, Analgesic, Antipyretic and Related Properties of Meloxicam, a New Non-steroidal Anti-inflammatory Agent with Favorable Gastrointestinal Tolerance," Inflamm. Res. 44:423-433 (1995)					
	AJ	Engelhardt, "Pharmacology of meloxicam, a new non-steroidal anti-inflammatory drug with an improved safety profile through preferential inhibition of COX-2," Brit. J. Rheumatology 1996:35 (suppl. 1): 4-12					
	AK	Distel et al., "Safety of Meloxicam: A Global Analysis of Clinical Trials," Brit. J. Rheumatology 1996:35 (suppl. 1):68-77					
	AL	Wojtulewski et al., "a Six Month Double-blind Trial to Compare the Efficacy and Safety of Meloxicam 7.5 mg Daily and Naproxen 750 mg Daily in Patients with Rheumatoid Arthritis," Brit. J. Rheumatology 1996:35 (suppl. 1):22-28					
	AM	Lipani, "Clinical Update of the Relative Safety of Nabumetone in Long-Term Clinical Trials," Inflammopharmacology (1995) Vol 3(4) pp. 351-361					
	AN	Swingle et al., "Preclinical Pharmacological Studies With Nimesulide," Drugs Exptl. Clin. Res. Vol. X (8-9) pp. 587-597					
	AO	Rabasseda, "Nimesulide: A Selective Cyclooxygenase 2 inhibitor Antiinflammatory Drug," Drugs of Today Vol 32, No.5 (1996), p9. 365-384					
	AP	Siebert et al., "Pharmacological and Biochemical Demonstration of the Role of Cyclooxygenase 2 in Inflammation and Pain," PNAS USA Vol.91 (Dec. 1994) pages 12013-12-17					
	AQ	Richardson et al., "The Clinical Implications of Inhibition of the Inducible Form of Cyclo-oxygenase," Drug Safety Vol. 15(4), pp. 249-260 (Oct. 1996)					
	AR						
	AS						
EXAMINER					DATE CONSIDERED		
<p>*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>							